

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Martin T. Gerber; John M. Swoyer	Confirmation No.	1410
Serial No.:	10/698,291		
Filed:	October 31, 2003	Customer No.:	28863
Examiner:	George C. Manuel		
Group Art Unit:	3762		
Docket No.:	1023-277US01		
Title:	IMPLANTABLE STIMULATION LEAD WITH FIXATION MECHANISM		

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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

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Commissioner for Patents  
Alexandria, VA 22313-1450

Sir:

Applicant respectfully requests a Pre-Appeal Brief Review based upon the Examiner's failure to establish a prima facie case of anticipation of claims 1, 3, 8, 9, 11-15, 20, 21, 22, 24, 29, 32-36, 41, 42, 53, 55, 58, 59, 60 and 62 under 35 U.S.C. § 102(e) and a prima facie case of obviousness of claims 2, 4, 5, 7, 10, 23, 25, 26, 28, 30, 31, 43-47, 52, 54, 56, 57, 61 and 63 under 35 U.S.C. § 103(a). As outlined below, the applied references fail to disclose or suggest one or more elements recited in Applicant's independent claims 1, 22, 42, and 53, as well as the dependent claims, such as dependent claims 3, 24, 45, and 55. For at least this reason, the rejections under 35 U.S.C. §§ 102(e) and 103(a) were improper.

For the sake of clarity, Applicant only presents arguments below with respect to independent claims 1 and 42 and dependent claims 3, and 10. Similar arguments apply to the other independent claims 22 and 53. By setting forth clear grounds of error with respect to claims 1, 3, 10, and 42, Applicant does not assert that this is the only error in the final Office Action dated June 23, 2008, nor does Applicant waive any additional arguments that may be asserted in an Appeal Brief.

***Independent Claim 1***

Claim 1 recites a neurostimulation lead comprising a lead body, a plurality of stimulation electrodes, and a fixation mechanism including one or more wire-like elements that are expandable to fix a lead body at a target tissue site. According to claim 1, the fixation mechanism is mounted between one of the electrodes and a proximal end of the lead body, and is axially displaced from the plurality of stimulation electrodes. Thus, claim 1 requires the lead to include a plurality of stimulation electrodes in addition to the fixation mechanism.

In support of the rejection of independent claim 1 in the final Office Action, the Examiner stated that Falwell et al. (U.S. Patent No. 7,255,695, hereinafter “Falwell”) disclosed each and every element of claim 1. The Examiner cited FIG. 14 of Falwell and characterized the braided conductive members 28B and 28C as “a plurality of stimulation electrodes” and the braided conductive member 28A as a fixation mechanism.<sup>1</sup> Falwell discloses that the conductive members 28A-2C are each made of a plurality of interlaced, electrically conductive filaments 34 that alone or in combination with other filaments may form isolated electrodes.<sup>2</sup> The Examiner appeared to rely on the fact that discrete sectors of each conductive member 28-28C may be activated independently to support the conclusion that the conductive members 28B, 28C of Falwell may be considered electrodes and the conductive member 28A may be considered an expandable fixation element that is axially displaced from the electrodes.<sup>3</sup>

This interpretation of Falwell, however, overlooks the fact that each conductive member 28A-28C disclosed by Falwell defines electrodes.<sup>4</sup> Thus, if the Examiner is characterizing the conductive members 28B and 28C as stimulation electrodes, the conductive member 28A would also reasonably be considered a stimulation electrode. In this way, all of the conductive members 28A-28C shown in FIG. 14 of Falwell define a plurality of electrodes, rather than a plurality of electrodes and a fixation mechanism. In contrast, Applicant’s claim 1 recites a lead that includes a plurality of stimulation electrodes in addition to a fixation mechanism that is axially displaced from the plurality of stimulation electrodes.

Each and every claim term must be given meaning, and the claimed invention as a whole must be considered.<sup>5</sup> Applicant’s claim 1 clearly requires a fixation mechanism that is axially displaced from, i.e., separate from, a plurality of stimulation electrodes. Falwell does not

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<sup>1</sup> Final Office Action dated June 23, 2008 at p. 3.

<sup>2</sup> Falwell at col. 5, ll. 60-62 and col. 6, ll. 16-21.

<sup>3</sup> Final Office Action dated June 23, 2008 at p. 3, citing col. 11, ll. 63-63 of Falwell.

<sup>4</sup> Falwell at col. 6, ll. 16-17.

<sup>5</sup> MPEP § 2141.02.

disclose a lead that includes both a plurality of stimulation electrodes and a fixation mechanism, but rather, only discloses a plurality of conductive members that may be used to detect electrical activity during mapping procedures or to apply energy during an ablation procedure.<sup>6</sup> The conductive member 28A cannot be a fixation mechanism that is axially displaced from a plurality of electrodes of the Falwell catheter, as proposed by the Examiner, because the conductive member 28A defines at least one of the electrodes.

Falwell also indicates that the conductive member 28A does not fix the catheter 10 at a tissue site, and, therefore, cannot be a fixation element of a lead. For example, with respect to FIG. 22, which illustrates a catheter shaft 12 placed in an ostium of a pulmonary vein 154, Falwell states that the conductive member 28 may be expanded to its deployed position and the catheter shaft 12 may be subsequently advanced into the pulmonary vein 154.<sup>7</sup> This indicates that the conductive member 28 does not fix the catheter 12 to tissue. Falwell also discloses that a lubricious coating may be applied to a conductive member 28 to reduce the possibility of vascular or atrial damage.<sup>8</sup> Moreover, Falwell discloses that a shroud may cover at least a portion of an expanded conductive member 28, where the shroud does “not reduce the mobility of braided conductive member 28.”<sup>9</sup> Accordingly, it appears that the conductive member 28 is intended to be mobile when expanded within tissue. In contrast, Applicant’s claim 1 specifically requires the fixation mechanism to include one or more wire-like elements that are expandable to fix a lead body at a tissue target site.

For at least these reasons, the Examiner failed to show that Falwell discloses a lead that includes a fixation element including one or more wire-like elements, where the fixation element is axially displaced from a plurality of stimulation electrodes. Accordingly, the Examiner’s rejection of independent claim 1 as being anticipated by Falwell was improper.

### ***Independent Claim 42***

Applicant’s independent claim 42 recites a method that comprises inserting a lead introducer into a patient, inserting a lead into the patient via the introducer, wherein the lead includes, among other things, a fixation mechanism that is axially displaced from a plurality of stimulation electrodes, and removing a restraint mechanism on the fixation mechanism, thereby

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<sup>6</sup> Falwell at col. 8, ll. 1-3.

<sup>7</sup> Falwell at col. 19, ll. 2-10.

<sup>8</sup> Falwell at col. 14, l. 64 – col. 15, l. 4.

<sup>9</sup> Falwell at col. 16, ll. 46-63; *see* FIGS. 20A-20C.

permitting wire-like elements of the fixation element to expand. As discussed above, the Examiner failed to demonstrate that Falwell discloses or suggests a lead that includes a fixation mechanism that is axially displaced from a plurality of stimulation electrodes.

In addition, the method of independent claim 42 requires removing a restraint mechanism on the fixation mechanism, thereby permitting the wire-like elements to expand. Falwell fails to disclose a restraint mechanism that permits the conductive member 28 to expand upon removal of the restraint mechanism. Instead, Falwell discloses that movement of a sheath 26 over an inner member 22 causes a conductive member 28 to expand radially.<sup>10</sup> Falwell also discloses that, “[a]s shaft 26 is moved distally, braided conductive member 28 emerges or everts from shaft 12.”<sup>11</sup> While Falwell discloses these techniques for causing the conductive member 28 to radially expand, none of these techniques includes a restraint mechanism that is removed in order to expand the conductive member 28. Thus, Falwell cannot anticipate independent claim 42.

### ***Dependent Claim 3***

Claim 3 specifies that the wire-like elements of the fixation element each have a proximal joint where a proximal end of the respective wire-like element meets the lead body and a distal joint where a distal end of the respective wire-like element meets the lead body. Claim 3 requires the distal joint to be weaker than the proximal joint. An example of a wire-like element including a weaker distal joint is shown in FIGS. 6A-6C of Appellant’s disclosure.

The Examiner failed to provide any support for the conclusion that claim 3 is anticipated by Falwell, despite rejecting claim 3 under 35 U.S.C. § 102(e) as being anticipated by Falwell. Falwell fails to disclose or suggest wire-like elements having a proximal joint and a distal joint that is weaker than the proximal joint, as required by claim 3. Falwell discloses that a proximal end of a conductive member 28 is anchored to the catheter shaft 12 using an anchor band 90, and the distal end is clamped to an activating shaft using another anchor band 92.<sup>12</sup> However, even if the conductive member 28A was a fixation mechanism, an assertion with which Applicant disagrees, Falwell does not discuss the joint strength of the filaments of the conductive member 28A, and lacks any disclosure that would have suggested the requirements of claims 3, 24, and 55. Therefore, Falwell cannot anticipate claim 3.

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<sup>10</sup> Falwell at col. 5, ll. 14-18.

<sup>11</sup> Falwell at col. 14, ll. 26-28.

<sup>12</sup> Falwell at col. 14, ll. 19-24 and FIGS. 16A-16C.

***Dependent Claim 10***

Claim 10 specifies that a restraint mechanism to restrain the wire-like elements of a fixation mechanism of claim 1 includes a stylet that is accommodated by an inner lumen of the lead. The Examiner failed to meet the burden of demonstrating that Falwell suggests the elements of claim 10. In support of the rejection of claim 10 as being obvious in view of Falwell, the Examiner asserted that “one of ordinary skill in the art would have found it obvious to construct the shaft portion 12 with a lumen to accommodate a stylet because a stylet is an art recognized actuating device and Falwell et al suggests a thumb wheel . . .”<sup>13</sup> However, claim 10 does not merely recite a stylet. Rather, claim 10 specifies that the restraint mechanism that restrains the wire-like elements of a fixation mechanism against expansion comprises the stylet. The Examiner appears to have disregarded these elements of claim 10.

Falwell fails to disclose or even suggest the restraint mechanism recited by claim 10. The thumb wheel that the Office Action refers to is merely used to deflect the distal end of the Falwell catheter.<sup>14</sup> Falwell does not disclose or even suggest that actuation of the thumb wheel restrains the filaments 34 of the conductive members 28A-C. For at least these reasons, Falwell cannot disclose or suggest a restraint mechanism that comprises a stylet, as recited by claim 10.

**CONCLUSION**

For at least the reasons stated above, the rejection of at least claims 1, 3, 10, and 42 was improper and must be reversed. Applicant requests a review and a panel decision that promptly resolves the issues in Applicants’ favor and eliminates the need for an Appeal Brief. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. Please charge any additional fees or credit any overpayment to deposit account number 50-1778.

Date:

By:

September 23, 2008  
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<sup>13</sup> Final Office Action dated June 23, 2008 at p. 4.

<sup>14</sup> Falwell at col. 4, ll. 61-63.